DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 12, 2014

AngioDynamics, Inc.
% Wanda Carpinella
Director, Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 01752

Re: K142593
Trade/Device Name: Angiovac Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: September 11, 2014
Received: September 15, 2014

Dear Wanda Carpinella,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
AngioVac Cannula

Indications for Use *(Describe)*
The AngioVac Cannula is indicated for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SECTION 5. 510(K) SUMMARY

510(k) SUMMARY (page 1 of 2)

Device Name: AngioVac Cannula **Date Prepared:** September 5, 2013

A. Submitter/Sponsor

AngioDynamics Inc.
26 Forest Street
Marlborough, MA 01752
Telephone Number/Fax: 508-658-7929/508-658-7976
Contact Person: Wanda Carpinella

B. Device Name

Trade Name:	AngioVac Cannula
Common/Usual names:	Cardiopulmonary Bypass Venous Cannula Extraction Catheter
Classification Names:	Catheter, cannula and tubing, vascular, cardiopulmonary bypass 21 CFR§870.4210, ProCode DWF
Classification:	Class II

C. Predicate Device(s)

Trade Name	510(k)	Company
AngioVac Cannula	K133445	Vortex Medical Inc. (acquired by AngioDynamics Inc.)

D. Device Description

The AngioVac device is a venovenous cannula with a balloon-actuated, expandable, funnel shaped distal tip that can be advanced through a 26 Fr sheath over a guidewire into the venous system percutaneously or via a surgical cut-down. During use, the cannula is connected to an extracorporeal circuit including an AngioVac Circuit, a commercially available centrifugal pump and bubble trap. A commercially available reinfusion cannula is placed for venous return (typically within internal jugular or one of the common femoral veins) and connected to the extracorporeal circuit. When the pump is started, suction is created, removing blood and debris from around the tip of the AngioVac

Cannula, circulating the blood through the filter, returning the blood to the patient via the venous return cannula. A benefit of the AngioVac Cannula is that it allows for removal of thrombus/embolic material, while minimizing blood loss via recirculation of blood through a standard extracorporeal (venovenous) bypass circuit. Target vessels for thrombus/embolus extraction include, but are not limited to, the iliofemoral vein, Inferior Vena Cava (IVC), Superior Vena Cava (SVC) and Right Atrium (RA). The device is provided in a straight and an angled (20^{o}) configuration.

E. Indication For Use

The AngioVac Cannula is indicated for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours.

F. Technology Characteristics

Within this current premarket notification, AngioDynamics is proposing to implement design modifications to the subject cannula to expand the product offering and/or to improve ease of use. Modifications include: Addition of an angled tip (20 degrees) cannula configuration; inclusion of radiopaque markers on the panels of the distal tip funnel to aid visualization; inclusion of stopcock on proximal end of the balloon inflation line; increased wall thickness of the balloon inflation line between cannula shaft and stopcock; modifications to the inner balloon; addition of a female quick disconnect to allow for an easier connection to the AngioVac Circuit; addition of hydrophilic coating on outside of obturator to facilitate obturator placement/removal from the cannula; and enhanced packaging configuration for improved presentation of product to sterile field (i.e., product packaged in tray instead of pouch).

With the exception of the hydrophilic coating on the obturator and inclusion of the radiopaque markers on the cannula distal tip, the proposed AngioVac Cannula is manufactured of the same materials used in the manufacture of the currently marketed predicate AngioVac Cannula. Additionally, there have been no changes to the shaft size or profile.

The proposed device has similar indications for use, materials, design, components and technological characteristics as the currently marketed AngioVac Cannula (K133445).

G. Performance Data

Comprehensive bench testing (integrity, functional performance and particulate evaluation) was performed to support substantial equivalence of the AngioVac Cannula. The AngioVac Cannula met all specified design and performance requirements. Additionally, the AngioVac Cannula has fulfilled the biocompatibility testing requirements identified in ISO 10993: Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process for an externally communicating device with circulating blood of a limited duration. Specifically the following tests were performed with acceptable results: cytotoxicity, sensitization, irritation, systemic toxicity and hemocompatibility.

Animal testing was also performed in accordance with 21 CFR Part 58. The results of the animal testing performed with the modified AngioVac Cannula have demonstrated the following:

- No evidence of hemodynamic compromise during use of the modified AngioVac Cannula
- No evidence of vessel injury noted on the final angiograms attributable to the placement and use of the AngioVac Cannula
- No abnormal gross or histological findings were noted in test vessel segments attributable to the placement and use of the AngioVac Cannula.
- No significant vascular response in these experimental conditions associated with the application of the modified AngioVac Cannula.

H. Clinical Testing

Not applicable

I. Conclusion

Based on responses to questions posed in the FDA's Decision Making Flow Chart, the proposed device is substantially equivalent to the predicate device.